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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/036,256	03/06/98	CARRIGAN	L 0725

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HM21/0609

EXAMINER

HAAS, T

ART UNIT	PAPER NUMBER
1649	3

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/036,256	Applicant(s) Lori Lisa Carrigan
Examiner Thomas Haas	Group Art Unit 1649

- Responsive to communication(s) filed on _____.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1-12 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-12 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- *Certified copies not received: _____.

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1649.

Claim Rejections - 35 USC § 112

1. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5, and 7 are vague and indefinite in the recitation of "ATCC accession No. _____" and "36A43". Dependent claims 2-4, 6 and 8-12 are included in this rejection because they each fail to correct the deficiency of the claim from which they ultimately depend.

The designation "36A43" is arbitrary and creates ambiguity in the claims. For example, the hybrid corn seed and plant disclosed in this application could be designated by some other arbitrary name or the assignment of the name "36A43" could be arbitrarily changed to designate another hybrid corn seed or plant. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970).

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Amending the claims so as to refer to the ATCC deposit accession number of the seed of corn hybrid line "36A43" would obviate this rejection.

2. Claims 5-8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-8 are vague and indefinite in their recitation of the term "capable of expressing all the "morphological and physiological characteristics of hybrid maize plant 36A43". This term is confusing in that it is unclear as to whether the plant cell of the claim is "capable of expressing all the morphological and physiological characteristics" due to the presence of genes encoding these characteristics or because the plant comprises the molecular machinery that is necessary for the expression of native and non-native genes.

3. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is unclear in that it appears the limitation "being of a tissue" is incorrect. While a cell can be of a tissue a protoplast cannot as protoplasts are not found *in planta*.

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4. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is unclear in the order of the recitation of the limitations. The phrase "representative seed having been deposited under ATCC accession number _____" could refer to the seed of '36A43' or to the seed of the plant regenerated from the tissue culture. Amendment of the claim to more clearly indicate that '36A43' has been deposited would overcome this rejection.

5. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention employs the hybrid corn seed designated '36A43'. Since the hybrid corn seed is essential to the claimed invention it must be both known and readily available to the public or can be made or isolated without undue experimentation. If the hybrid corn seed is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of hybrid seed that when planted will produce corn hybrid 36A43. The specification does state that "the Applicant(s) will make available to the public without restriction a deposit of at least 2500 seeds of hybrid 36A43 with the American Type Culture Collection" (page 27, lines 23-32) and will meet

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all conditions of 37 CFR § 1.801-1.809; however, the deposit of '36A43' has not been perfected. The specification does not disclose a repeatable process to obtain the exact hybrid corn seed designated '36A43' and it is not apparent if the seed is both known and readily available to the public. Thus, a perfected deposit may be used for enablement purposes. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

6. Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 5-7 are drawn to a tissue culture that "regenerates plants capable of expressing all the morphological and physiological characteristics of said hybrid maize plant 36A43". The specification discloses the physiological and morphological characteristics of inbred corn line '36A43' and, via the deposit of seed capable of producing this inbred line, enables the person having skill in the art the ability to make and use the invention. The specification does not

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describe other plants having all the physiological and morphological characteristics of inbred corn line '36A43', nor does it enable the person having skill in the art to make a line having all the physiological and morphological as the parental material is propriety and the selection criteria employed to make '36A43' is not disclosed. Clearly the claimed invention is broader than that which is enabled by the deposit of '36A43' and as such is not enabled by said deposit. In this regard the decision in *Ex parte Tanksley* (BdPatApp&Int) • 37 USPQ2d 1382 is considered instructive in which claims which first appear enabled are found indefinite and broader than that warranted by the deposit of material which enables Applicant's specific contribution to the art. In this case Applicant's specific contribution would appear limited to that which has been deposited, to the extent that the claims under question are interpreted to consist of the deposited inbred line, in which the superficial name '36A43' is absent. That is, the claims may be considered to cover the seed, plants and hybrids made by the use of '36A43' that have not been deposited with the ATCC so long as that seed, plants and hybrids have all the physiological and morphological characteristics of '36A43' which have been deposited. Alternatively, the claims may be interpreted to include trivial modification of enabled seed, plants and hybrids of '36A43' in which the same retain all the physiological and morphological characteristics of inbred corn line '36A43', its parts and hybrids. The specification does not teach the metes and bounds of such modifications and as such is claims 5-8 are considered broader than that which is enabled by the deposits of seed of '36A43'.

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Claim Rejections - 35 USC § 103

7. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan et al. (Planta (1985) 165:322-332).

Claims 5-7 are directed to a tissue culture of regenerable cells wherein the tissue culture regenerates plants capable of expressing all the morphological and physiological characteristics of hybrid maize plant 36A43.

Duncan et al. teach the regeneration of maize plants from tissue culture (see entire document).

Duncan et al do not teach tissue culture derived from hybrid maize line 36A43.

The regeneration of corn plants from tissue culture was well known in the art at the time the invention was made. It would have been obvious to one of ordinary skill in the art at the time the invention was made to regenerate corn plants from tissue culture as Duncan et al. teach just such a method. One of ordinary skill in the art would recognize that these corn plants would be capable of expressing both native and heterologous genes. Thus, said corn plants are capable of expressing all of the physiological and morphological characteristics of hybrid line 36A43. Given the advanced state of the art of plant cell and tissue culture, it would be obvious to one of ordinary skill in the art the selection of the particular plant line to be used in such a tissue culture and plant regeneration method is an optimizations of design parameters. Thus, claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan et al.

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Conclusion

8. No claims are allowed.
9. Claims 1-4 and 8-12 are considered free of the prior art based on the failure of the art to teach or suggest a hybrid corn line with the characteristics of 36A43.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Haas whose telephone number is (703) 305-7270. The examiner can normally be reached on Mon.-Fri. from 7:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Robinson, can be reached on (703) 308-2897. The fax phone number for the organization where this application or proceeding is assigned is (703) .

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**GARY BENZION, PhD.
PRIMARY EXAMINER
GAU 1649**